

FOOD AND DRUG ADMINISTRATION

Center for Tobacco Products (CTP)

Tobacco Products Scientific Advisory Committee (TPSAC)

August 30, 2010

Questions to the Committee

1. For carcinogens, do you recommend that constituents that meet the following criteria be included in the initial HPHC list? (Vote Yes/No):

- Identified as a known or probable human carcinogen by either IARC, EPA, or NTP

This would include the following categories

- IARC Group 1 and Group 2A (Sufficient evidence in humans or sufficient evidence in animals and strong mechanistic data in humans; limited evidence in humans and sufficient evidence in animals)
- EPA -- “known human carcinogen,” “likely human carcinogen,” or “probable human carcinogen”
- NTP -- “human carcinogen,” “reasonably anticipated to be a human carcinogen”

2. For carcinogens, do you recommend that constituents that meet the following criteria be included in the initial HPHC list? (Vote Yes/No):

- Identified as possible human carcinogen by IARC or EPA; identified by NIOSH as a potential occupational carcinogen

This would include

- IARC Group 2B – limited evidence in humans and less than sufficient evidence in animals
- EPA -- “possible human carcinogen”

3. For adverse respiratory or cardiac effects, do you recommend that constituents that meet the following criteria be included in the initial HPHC list? (Vote Yes/No):

- Identified by EPA or ATSDR as having adverse respiratory or cardiac effects

IARC = International Agency for Research on Cancer

EPA = Environmental Protection Agency

NTP = National Toxicology Program

4. For reproductive or developmental toxicants, do you recommend that constituents that meet the following criteria be included in the initial HPHC list? (Vote Yes/No):
- Identified by the California EPA as a reproductive or developmental toxicant
5. For chemical or chemical compounds with potential abuse liability, do you recommend that constituents that meet the following criteria be included in the initial HPHC list? (Vote Yes/No):
- Based on peer-reviewed literature, evidence of at least two of the following:
 - Central Nervous System activity
 - Animal drug discrimination
 - Conditioned place preference
 - Animal self-administration
 - Human self-administration
 - Drug “liking”
 - Withdrawal
6. For smokeless tobacco products, do you recommend that constituents that meet the following criteria be included in the initial HPHC list? (Vote Yes/No)
- Constituents banned in food
7. Do you recommend the following smoking machine regimens be used when measuring HPHC? (Vote Yes/No):
- Both ISO and Canadian Intense methods